

**Philip Morris, USA  
Pilot Total Exposure Study  
Proposed Timeline**

Study No.	8450		
	Contact	Projected Date	Actual Date
Draft Protocol to Philip Morris	T. Janisch	01/12/01	01/12/01
Protocol Comments to CRU	J. Oey	01/31/01	02/01, 02/06/01
Revised Protocol to Philip Morris	T. Janisch	02/15/01	02/15/01
Draft Contract to Covance	L. Carchman	02/23/01	02/28/01
Submit Advertisement to IRB	M. Larson	02/26/01	02/26/01
Analytical Info to CCLS	M. Bentley, M. Feit, J. Eberhard	03/02/01	03/16/01
Draft Interviewer's Instructions to Philip Morris	R. Chaouki	03/09/01	03/09/01
Revised Contract to Philip Morris	J. Milhone	03/07/01	03/07/01
Revised Draft Protocol, Questionnaire, Diary to Philip Morris	T. Janisch, M. Larson	03/09/01	02/23/01 (diary) 03/09/01 (protocol/questionnaire)
Conference Call to Discuss Contract	J. Milhone, J. Schultz, M. Ginsky, L. Carchman, PM Lawyer	03/09/01	03/08/01
CCLS Specifications to CRU	P. Warner	03/09/01	03/09/01
RAP to Philip Morris	R. Chaouki	03/12/01	03/12/01
Finalize Contract	J. Milhone, L. Carchman	03/26/01	
Revised Draft Informed Consent to Philip Morris	M. Larson	03/19/01	03/19/01
Draft CRFs to Philip Morris	M. Larson	03/19/01	03/19/01
Protocol, Questionnaire, Diary, and Informed Consent Comments to CRU	J. Oey	03/23/01	03/19/01 (protocol) 03/23/01 (questionnaire) 03/30/01 (diary) 03/25/01 (informed consent)
RAP Comments to CRU	B. Nelson	04/02/01	04/02/01
Final Draft Questionnaire to Philip Morris	R. Chaouki	04/04/01	04/04/01
Finalize Protocol/Questionnaire	T. Janisch	04/16/01	04/06/01 (Questionnaire) 04/17/01 (Protocol)
Covance to Approve CCLS Specifications	M. Larson, M. Bentley	04/09/01	03/20/01

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**Pilot Total Exposure Study**  
**Proposed Timeline (Continued)**

Study No.	8450		
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CRF comments to CRU	J. Oey	04/09/01	04/09/01
Submit Protocol, Questionnaire, Diary, and Informed Consent to IRB	M. Larson	04/04/01 (Informed Consent) 04/18/01 (Protocol/ Questionnaire/Diary)	04/04/01 (Informed Consent) 04/18/01 (Protocol/ Questionnaire/Diary)
IRB Meeting	M. Larson	04/09/01 (Informed Consent) 04/23/01 (Protocol/ Questionnaire/Diary)	04/09/01 (Informed Consent) 04/23/01 (Protocol/ Questionnaire/Diary)
Draft Data Management Plan to Philip Morris	R. Chaouki	04/27/01	04/27/01
2 <sup>nd</sup> Draft RAP to Philip Morris	R. Chaouki	05/02/01	05/02/01
Study Initiation	M. Larson	05/01/01	05/01/01
Draft Data Management Plan Comments to CRU	J. Oey	05/04/01	05/04/01
2 <sup>nd</sup> Draft RAP Comments to CRU	B. Nelson	05/23/01	05/23/01
LVO	M. Larson	06/18/01	06/18/01
Finalize RAP	R. Chaouki	08/03/01	09/13/01
Analytical Method Validation Complete	K. Phillips	08/24/01	10/12/01
Source Document Info. Transferred to CRFs	M. Larson	07/23/01	07/23/01
CRFs Delivered to Data Management	M. Larson	08/06/01	07/27/01
CRFs Entered into Data Base	R. Chaouki	08/16/01	08/16/01
CRF Edit Checks Completed	R. Chaouki	08/30/01	08/30/01
CRF Queries Resolved	M. Larson	10/05/01	10/05/01
Bioanalytical Data Available	K. Phillips	03/01/02	
Bioanalytical Reports	K. Phillips	03/01/02	
Data Base Lock	R. Chaouki	04/05/02	
Draft CTR	T. Janisch	05/24/02	
Final CTR	T. Janisch	07/19/02	